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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

20 FEB 1987

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Screen for Ciba-Geigy Corporation's PP#7H5532 for Metalaxyl (Ridomil®) on Dried Hops.

FROM: Nancy Dodd, Chemist *Nancy Dodd*
Tolerance Petition Section II
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C)

THRU: Charles L. Trichilo, Ph.D., Chief
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C)

TO: Anne Lindsay
Office of Pesticide Programs

and

Lois Rossi, P.M. 21
Fungicide-Herbicide Branch
Registration Division (TS-767C)

NO
EXPEDITE

RCB has been asked to screen Ciba-Geigy's submission for residues of metalaxyl on dried hops at 10.0 ppm. Tolerances are established (40 CFR 180.408, 21 CFR 561.273, and 21 CFR 193.277) for metalaxyl on dry hops at 2 ppm (food additive tolerance) and green hops at 0.5 ppm (PP#1F2537/FAP#1H5311). This petition is submitted at the request of the West German government in order to allow importation of metalaxyl-treated hops into the U.S.A. Higher tolerances are needed on hops imported from Germany since use patterns there differ from those in the U.S.A.

RCB concludes the following concerning the present submission:

1. The nature of the residue is adequately understood.
2. Adequate analytical methods are available in Pesticide Analytical Method - Volume II for analysis of metalaxyl and its metabolites on hops.
3. RCB will not be able to evaluate the adequacy of the proposed 10 ppm tolerance for metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety and the N-(2-hydroxymethyl-6-methylphenyl)-N-(methoxyacetyl)alanine methyl ester from the available residue data. The analytical method used by the petitioner to obtain residue data

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on hops determines parent compound only. If the submitted methods (REM 21/76 and REM 1/80 - determining only the parent compound) were used to generate residue data, then the petitioner should submit additional residue data on samples (reserve samples, if available) which are analyzed by the PAM-II procedure or another procedure which determines parent and the metabolites which are included in the tolerance expression. Thus, a tolerance of 10 ppm may not be adequate. Also, the petitioner should submit method REM 21/77/IA 2 which appears to have been used to analyze some samples. Storage intervals between sampling and analysis and storage conditions should be reported for all samples.

4. Storage stability data for strawberries stored 1-14 months ((PP#6F3337, M. Firestone, 2/21/86) and for potatoes and tobacco stored at least 18 months (PP#1F2500, P. Errico, 3/9/82) indicate that residues of metalaxyl and its metabolites determined as 2,6-dimethylaniline are stable for at least 18 months when stored at 5°F. This indicates that storage stability data are adequate for hops samples which were stored for 18 months or less.
- 5a. Spent hops are an animal feed item comprising up to 5% of the diet in beef and dairy cattle. The residue ingestion level of cattle from the proposed crop tolerance is < 0.5 ppm (10 ppm tolerance x 5% of the feed). Brewers' grain, the by-product of the beer brewing industry which includes hops, is also an animal feed.

U.S. tolerances for metalaxyl are established on meat and milk at the following levels:

- 0.4 ppm fat, kidney, and liver of cattle, goats, hogs, horses, poultry, and sheep
- 0.05 ppm meat and meat by-products (except kidney and liver) of cattle, goats, hogs, horses, poultry, and sheep
- 0.02 ppm milk

Feeding studies are available on cows at levels of 0.5 to 15 ppm for 40 days and 75 ppm (¹⁴C) for 28 days. Residues in cows were as high as 0.22 ppm in liver and 0.83 ppm in kidney resulting from the 15 ppm feeding level. No detectable residues were found in meat (<0.05ppm) or milk (<0.01 ppm). (PP#1F2500, P. Errico, 3/9/82; PP#1G2532/FAP#1H5314, R. Loranger, 2/5/82; PP#3F2847, M. Nelson, 7/7/83)

RCB concludes that the established tolerance of 0.02 ppm is adequate to cover residues in milk resulting from the proposed use. The established tolerances of 0.4 ppm for fat and liver and 0.05 ppm for meat and meat by-products of cattle, goats, hogs, horses, poultry, and sheep are also adequate.

However, if imported dried hops are extracted to produce hop extract for beer and spent hops which may be fed to animals, RCB foresees that the established tolerance of 0.4 ppm should be raised to about 1.0 ppm for kidney of cattle, goats, hogs, horses, poultry, and sheep. However, it is our understanding that an agreement will be made with FDA and the hops importers to preclude the use of imported hops for the production of hops extract and spent hops. No increase in the kidney tolerance is needed because of the feeding of brewers' grain.

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- 5b. A feed additive tolerance should be proposed for spent hops at the same level as for dried hops. The spent hops tolerance is needed to cover residues in brewers' grain which is an animal feed.
- 5c. Since there are no poultry feed items, no secondary residues are expected to occur in poultry and eggs as a result of this use.

The petitioner needs to provide the following data/information in order to obtain a tolerance:

1. The petitioner should submit additional residue data on samples (reserve samples, if possible) which are analyzed by the PAM-II procedure or another procedure which determines parent and its metabolites containing the 2,6-dimethylaniline moiety and N-(2-hydroxymethyl-6-methylphenyl)-N-(methoxyacetyl)alanine methyl ester.
2. The petitioner should submit method REM 21/77/IA 2 which appears to have been used to analyze some samples.
3. The petitioner should propose a feed additive tolerance for spent hops at the same level as for dried hops. The spent hops tolerance is needed to cover residues in brewer's grain which is an animal feed.
4. The petitioner should provide specific information on how dried hops were actually reconstituted (volume of water; soaking time) prior to extraction with organic solvent.
5. The petitioner should indicate in his submission (Section B) the maximum grams active ingredient/ha/season so that RCB can evaluate the residue data.
6. The petitioner will have to address any additional data deficiencies which may be noted upon completion of the full RCB review. RCB has identified for the purposes of this screen only the obvious deficiencies.

Recommendations

RCB recommends that the registrant read carefully the issues outlined above since RCB is concluding that the subject submission has failed the requested screen.

cc: R.F, S.F., Circ., Reviewer- N. Dodd, PP#7H5532, Jim Akerman, Anne Barton
RDI:J.H.Onley:2/10/87;RDSchmitt:2/10/87
TS-769;RCB:CM#2:RM810:X1681:N.Dodd:N.Dodd:2/11/87